

Plenary Session 2: Freeze-Stable Vaccines

Next-Generation Vaccine Delivery Technology Meeting
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Freeze-protection technology: For aluminum adjuvant-containing vaccines

Technology Description:

Inclusion of a safe and commonly used excipient in the vaccine formulation (e.g., propylene glycol, polyethylene glycol 300, or glycerin).

Vaccine 27 (2009) 72–79

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 **Vaccine** 

Journal homepage: www.elsevier.com/locate/vaccine

Development of a freeze-stable formulation for vaccines containing aluminum salt adjuvants

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Freeze protection: Mechanism of action

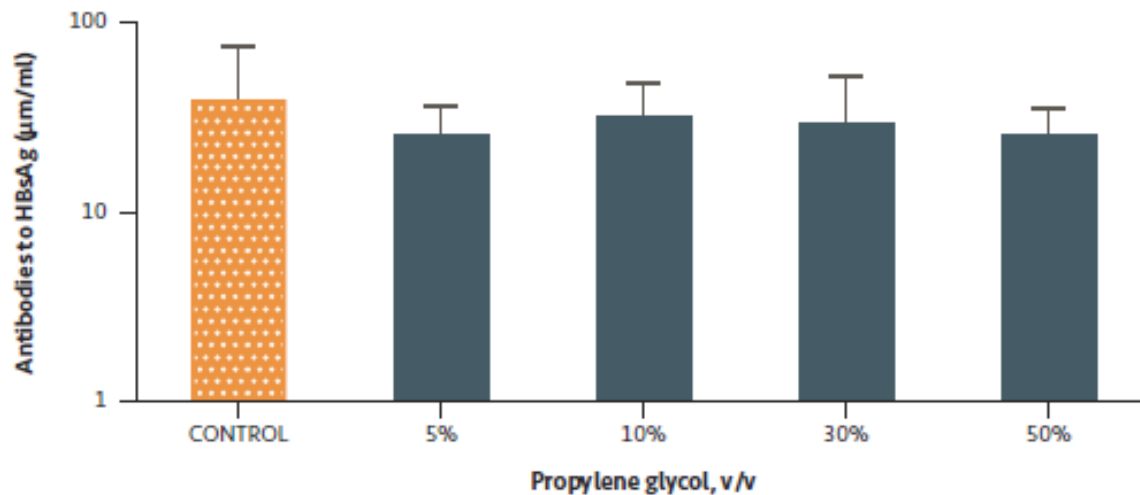
Overview:

- At low concentrations (5 to 10 percent), the excipients do not necessarily prevent freezing but still prevent freeze damage by inhibiting agglomeration of particles—even following exposure to multiple freeze-thaw cycles at temperatures as low as -80°C .
- Freeze-stable formulations validated by vaccine producers in laboratory and preclinical studies with hepatitis B (HepB), diphtheria-tetanus-acellular pertussis, diphtheria-tetanus-whole cell pertussis (DTwP) and DTwP-HepB-Hib vaccines.



PATH/Scott Areman

Freeze protection: Hepatitis B vaccine



Effect of 5% to 50% propylene glycol on HepB vaccine immunogenicity (in mice) after three cycles of exposure to -10°C to 4°C (at least 18 hours at each temperature) or stored at 4°C as a control.

Jones Braun, Jezek J, Petersen S, et al. *Vaccine*. 2009; 27:72–79.

Freeze protection: Benefits and challenges

Benefits:

- For vaccine manufacturers:
 - Enhances product features and competitiveness; reduces risk of recalls.
 - Cost for key excipients is approximately \$0.001 per dose.
- Benefits to vaccine users:
 - Improves vaccine effectiveness, reduces wastage and cost, and may enable the use of ice and domestic refrigerators.

Challenges:

- Needs to be integrated into vaccines during product development.
- Lack of incentives for vaccine producers to formulate freeze-stable vaccines.



PAT/Patrick McKern

Freeze protection: Opportunities and way forward

Global Public Health Challenge:

- Strong evidence that freeze-sensitive vaccines are exposed to freezing temperatures during storage and transport.

Technology Availability:

- PATH has placed the freeze-protection technology in the public domain for use by all vaccine producers.
- All new vaccines containing aluminum, including combination vaccines (e.g., with IPV), could benefit.
- Incentives required for vaccine producers/developers to incorporate the technology.

